



**Australian Government**  
**Department of Health and Ageing**



Australia and New Zealand Horizon Scanning Network

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TERRITORY GOVERNMENTS OF AUSTRALIA  
AND THE GOVERNMENT OF NEW ZEALAND

# **Horizon Scanning Technology**

## **Prioritising Summary**

### **NxStage System One home dialysis for patients waiting for kidney transplantation**

**November 2008**



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# PRIORITISING SUMMARY

**REGISTER ID:** 000182

**NAME OF TECHNOLOGY:** NxSTAGE SYSTEM ONE HOME DIALYSIS

**PURPOSE AND TARGET GROUP:** FOR PATIENTS WAITING FOR KIDNEY TRANSPLANTATION WHO REQUIRE REGULAR DIALYSIS

## STAGE OF DEVELOPMENT (IN AUSTRALIA):

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established  |
| <input type="checkbox"/> Experimental             | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational          | <input type="checkbox"/> Should be taken out of use   |
| <input type="checkbox"/> Nearly established       |   |

## AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- |   |             |
|---|-------------|
| <input type="checkbox"/> Yes            | ARTG number |
| <input checked="" type="checkbox"/> No  |             |
| <input type="checkbox"/> Not applicable |             |

## INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
USA		✓	

## IMPACT SUMMARY:

NxStage Medical markets the NxStage System One for the purpose of transportable home dialysis for patients requiring renal replacement therapy.

## BACKGROUND

Chronic kidney disease is a major burden to the Australian healthcare system and is rapidly increasing in its prevalence. The state where kidney function is reduced below a threshold, that is where the patient will die unless their kidney function is replaced by a transplant or dialysis, is known as end stage kidney disease (ESKD). Dialysis and kidney transplant are together known as renal replacement therapy (RRT). Dialysis takes one of two forms: haemodialysis (blood is cleaned outside the body in a specialised machine) and peritoneal dialysis (blood is cleaned in the peritoneal cavity via use of a specialised solution placed into the peritoneal cavity). The majority of haemodialysis is generally carried out at a hospital or specialised clinic. Due to the large size of Australia and its low population density, the rate of home haemodialysis

is one of the highest in the world. The portable and self contained NxStage System One allows home-based haemodialysis. The NxStage System One is the size of a computer monitor and weighs approximately 30 kg. The unit does not need the water supply modifications that other home haemodialysis units require as it uses bagged sterile dialysate fluid. Alternatively, with accessories, the NxStage System One can produce dialysate fluid from purified tap water. The unit is also portable allowing dialysis outside of the home. This device may improve the quality of life of haemodialysis patients.

### **CLINICAL NEED AND BURDEN OF DISEASE**

In Australia one in three people are at risk of developing chronic kidney disease (CKD), with one in seven having CKD and one in 1,400 requiring dialysis or a kidney transplant. CKD is the 7<sup>th</sup> highest cause of death in Australia. The need for dialysis is increasing within the Australian population due to the increasing incidence of diabetes and the ageing population. Over 25 years Australian population growth has been less than 40 per cent yet the need for dialysis and kidney transplants has increased 400 per cent. In 2006 there were 9,182 dialysis patients in Australia (Kerr et al 2008). In 2005 around 13 per cent (800) of haemodialysis patients dialysed at home (KHA 2005). It is estimated that the current cost of providing dialysis for one patient for a year costs AUD\$60,000. Including transplants the cost of end stage kidney disease is estimated to be at least AUD\$570 million annually (KHA 2006b; KHA 2006a).

### **DIFFUSION**

There was no evidence found to indicate the diffusion of this device into the Australian market

### **COMPARATORS**

Despite Australia and New Zealand having the highest rates of home dialysis in the world, the majority of dialysis is still centre (hospital or clinic) based (Agar 2008). It is increasingly recognised that centre based haemodialysis is not the optimum patient management strategy regarding both health outcomes and patient survival times (ANZDATA 2006). It is currently thought that the optimum strategy for maximal health and lifespan is nocturnal haemodialysis where the patient has haemodialysis more frequently and for longer periods (8 hours a night up to 6 or 7 times a week). This increased frequency and duration paradigm has been shown to be associated with decreases in mortality and RRT associated morbidity such as cardiovascular disease (Masterson 2008).

### **SAFETY AND EFFECTIVENESS ISSUES**

A study of 19 patients assessed the basic markers of haemodialysis for patients using the NxStage System One and reported that greater than 85 per cent achieved recommended urea clearance. Medications for secondary complications of chronic

kidney disease (high blood pressure, anaemia) were reduced in more than 50 per cent of patients. Patients reported increased energy, appetite, sleep quality and fewer symptoms when treated with the NxStage System One (Floramo 2006) (Level III-3 Intervention evidence).

A small study of four paediatric patients has assessed a program of frequent dialysis (6 times weekly), rather than the standard centre based treatment of three times weekly. Patients were on standard dialysis before the trial, which ran for 16 weeks. Over the trial period the patients showed reductions in blood pressure and were removed from anti-hypertensive medications. Patients also had improved serum phosphorous levels without increased medication. A negative side effect attributed to the more frequent dialysis regimen was the lower haematocrit<sup>1</sup> levels which required increased erythropoietin (Goldstein et al 2008) (Level III-3 Intervention evidence).

A small, multi-centre prospective cross-over treatment study (n=32) was conducted comparing the NxStage System One to centre based dialysis. The treatment protocol consisted of eight weeks of centre treatment (6 conventional dialysis sessions per week), a two week in centre transition treatment (6 NxStage System One dialysis sessions per week), and an eight week at home treatment (6 NxStage System One dialysis sessions per week). There were significantly more adverse events associated with the centre based treatment (5.3 adverse events<sup>2</sup> per 100 treatments) versus the home based NxStage System One treatment (2.1 adverse events per 100 treatments; p=0.007). Compared to baseline, patients experienced weight gain, had reduced blood pressure and reduced use of anti-hypertensive medications. This effect was not solely due to the NxStage System One device as the effect was also noted in the in centre based part of the study. This was attributed to increased dialysis treatments (6 /week) over the average baseline dialysis treatments (3 / week) (Kraus et al 2007) (Level III-2 Intervention evidence).

The data on the NxStage System One are from small, low to medium quality studies. Despite this the NxStage System One shows promise for improved patient health and convenience. Additionally it is well established that standard home dialysis is far more cost effective than centre based treatment. If this holds true for the NxStage System One then it may have a large impact on a rapidly growing population of patients requiring RRT.

## **COST IMPACT**

The manufacturer of the NxStage System One was contacted for pricing on the device but no information was forthcoming at the time of publication. No research literature examined the costs associated with NxStage System One utilisation.

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<sup>1</sup> A measure of the level of red blood cells in the blood.

<sup>2</sup> Adverse events included back pain, arthralgia, night cramps, neck pain, dysgeusia, dizziness, tremor, sinusitis, nausea.

## **ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

No issues were identified/raised in the sources examined.

## **OTHER ISSUES**

A large trial of 5,000 RRT patients is underway with the NxStage System One (6 dialysis periods per week) being compared to conventional centre based haemodialysis (3 dialysis periods per week). The trial will run over three years (Jaber et al 2008).

## **SUMMARY OF FINDINGS**

The NxStage System One is a promising device which meets most of the current optimum treatment paradigm criteria, that is: enables frequent use, is home based and requires no home modifications. In addition, the device is portable and seems to compare favourably with existing conventional therapy.

## **HEALTHPACT ACTION:**

The NxStage System One provides greater versatility for patients requiring dialysis and may be especially useful in rural and remote populations. Based on the high need and potential great gains from the successful introduction of such a device into the Australian market and that there is a large ongoing trial it is recommended this the NxStage System One be monitored.

## **NUMBER OF INCLUDED STUDIES**

Total number of studies

Level III-2 Intervention evidence	1
Level III-3 Intervention evidence	2

## **REFERENCES:**

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**SEARCH CRITERIA TO BE USED:**

Nxstage System One

Clinical trial

Haemodialysis

Home dialysis

Kidney failure